DIAGNOSTICS

by Emily Arakaki
Biotechnology and Diagnostics, Trade Development

This rapidly growing industry includes *in vitro* diagnostic (IVD) tests that examine bodily fluid or tissue samples to detect, diagnose, and manage medical conditions; and *in vivo* diagnostic substances that are taken internally to enhance the images of targeted organs or functions during a diagnostic imaging procedure.

The U.S. Food and Drug Administration has approved hundreds of biotech-derived tests, including tests that keep the blood supply safe from the AIDS and hepatitis viruses as well as allow diagnoses of genetic conditions. Meanwhile, DNA "fingerprinting" has dramatically improved forensic investigations, while DNA chips are transforming research by allowing us to test tens of thousands of genes at one time.

In addition to medical applications, diagnostic products are used to test microbial contamination of foods and water; and pollutants in air, water, and soil. According to the U.S. Census Bureau, U.S. diagnostic test sales totaled $9.5 billion in 2000. Industry observers estimate that sales will increase 7 percent annually, propelled by knowledge gleaned from the mapping of the human genome and proteins that underlie diseases, and the increase in the elderly population from the aging of the baby boom generation. Sales of test kits to detect the presence of foods derived through biotech are increasing as a result of foreign government labeling regulations on biotech foods.

These developments are producing steady gains for U.S. exports. The United States is the world's leading supplier of diagnostic tests, accounting for an estimated 40 percent of global output. In 2001, IVD exports totaled $3 billion, amounting to a $1.9 billion trade surplus. The major overseas destinations are Japan, the United Kingdom, Germany, Canada, and France.

COMMERCE ACTIVITIES IN BIOTECHNOLOGY AND DIAGNOSTICS

The primary mission of the U.S. Commerce Department's International Trade Administration (ITA) is to assist U.S.-based companies in expanding export and other commercial opportunities while reducing trade barriers. For example, ITA offers a variety of services including export counseling at offices located throughout the United States and at embassies abroad, as well as research on leading foreign markets. The Chemicals, Pharmaceuticals and Biotechnology Division (CPBD) in ITA is also participating in a public-private partnership with the Advancing California's Emerging Technologies incubator in Alameda, the Bay Area World Trade Center, and California's Commerce, Trade and Technology Agency, to help new companies in the state enter the European market. This effort, partially funded under a matching grant awarded by the Commerce Department under the Market Development Cooperator Program (MDCP), began with a workshop on the EU market held in Oakland in April, and will include trade missions such as Medica in Germany this November. For further information about the MDCP and applying for a grant, visit www.export.gov/mdcp.

Technological progress often presents new regulatory, scientific, and social issues. It is not uncommon for government regulations, in the United States or elsewhere, to trail introduction of new products. The Department of Commerce can assist U.S. biotechnology and diagnostics companies to obtain foreign regulations and contacts, or assist foreign buyers and U.S. embassies in locating American suppliers. For example, CPBD staff worked with Commercial Service posts and government ministries in successfully assisting a large firm in entering the Mexican market for a biotech-derived enzyme used in food production, and in exporting cell lines to France. Several years ago, when Chinese producers were hit by a serious contamination problem affecting human albumin production, CPBD located alternative U.S. suppliers. CPBD also helped set up a sales mission to centers of excellence in South America for a U.S. producer of reagents used in DNA testing, and is currently working with the diagnostic industry in obtaining clarifications on regulatory approval procedures in Asia.

On a broader scale, ITA is working with other government agencies to ameliorate country practices that impede U.S. exports. The leading trade barriers for biotech-derived products are restrictions on regulatory approvals and labeling of biotech foods, inadequate intellectual property rights, and price controls on biomedical products. (To view the most recent report on trade barriers, visit www.ustr.gov/reports/nte/2002/index.htm.) ITA is also working to ensure that new international standards or guidelines under consideration in the Codex Alimentarius and the Biosafety Protocol, which affect approval processes for biotech-derived foods and labeling requirements, are scientifically based and are no more trade restrictive than necessary. To meet the challenges raised by biotechnology, CPBD recently added a second person to its staff. U.S. companies seeking relief from trade barriers should feel free to ITA's Trade Compliance Center or CPBD trade specialists. ■

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Report trade complaints to the Trade Compliance Center.

Additionally, the Commercial Service publishes many useful market research reports, which can be found at www.usatrade.gov.